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EDX Epi-Scan

130 Main Road
Huntsville, AL 35811
256-858-6666

SUMMARY

Submitter's name:	EDX Epi-Scan
Address:	130 Main Road Huntsville, AL 35811
Phone:	256-858-6666
Name of contact person:	Greg Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 fax: 949-552-2821
Date the summary was prepared:	September 4, 2003
Name of the device:	EDX Epi-Scan
Trade or proprietary name:	EDX Epi-Scan
Common or usual name:	Galvanic Skin Response Measurement Device
Classification name:	Galvanic Skin Response Measurement Device

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

K874850, Epi-Scan Selective Tissue Conductance Meter submitted by EDX Epi-Scan Inc

Description of the device:

The development of the Epi-Scan P100 has been based on the combined principles of instrumentation and the electrophysiological effects of innervation of the sweat glands. This provides a noninvasive, painless instrument system fore the quantitative measurement of Selective Tissue Conductance, which has been operationally defined as "...the relative ability of biological tissue to conduct a weak (DC) electrical signal, which is applied for a *selected* period of time to a *selected*, limited and restricted surface area of that tissue..." and which shares those same neuroanatomic reflex

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pathways as other tests of sympathetic skin activity or regional perspiration levels.

Indications:

For the measurement of galvanic skin response.

Summary of the technological characteristics of our device compared to the predicate device:

The Epi-Scan Selective Tissue Conductance Meter, K874850 and Epi-Scan P100 were compared in the following areas and found to have similar technological characteristics and to be equivalent.

Indications for use
Skin conductance range
Display
Components
Standards met
Software

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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EDX Epi-Scan
c/o Mr. Greg Holland
Regulatory Specialists, Inc.
3722 Avenue Sausalito
Irvine, California 92606

Re: K032935
Trade/Device Name: Epi-Scan P100
Regulation Number: 21 CFR 882.1540
Regulation Name: Galvanic skin response measurement device
Regulatory Class: II
Product Code: GZO
Dated: October 23, 2003
Received: October 31, 2003

Dear Mr. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032935

Device Name: Epi-Scan P100

Indications For Use:

For the measurement of galvanic skin response.

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032935